

REMARKS

This paper is responsive to the final Office Action mailed April 29, 2005. Claims 1-33 and 42-63 were pending in the application, claims 1, 2, 20-33, 42, and 44 were under consideration, and claims 3-19, 43, and 45-63 were withdrawn by the PTO as directed to a non-elected invention.

In this paper, claims 1, 10, 12-16, 20, and 44 are amended, claims 3-9, 11, 17-19, and 45-47 are cancelled without prejudice to Applicants' right to pursue the subject matter of the cancelled claims in one or more related continuation, divisional, or continuation-in-part applications, and claims 64 and 65 are presented for consideration. Thus, following entry of the present amendment, claims 1, 2, 10, 12-16, 20-33 and 42-44, and 48-65 are pending, claims 1, 2, 20-33, 42, 44, and 64-65 are under consideration, claims 3-9, 11, and 17-19 are cancelled without prejudice, and claims 10, 12-16, 43 and 48-63 stand withdrawn.

I. Interview Summary

On July 15, 2005, Applicants' representatives Dr. Rahul Pathak and Mr. David C. Pauling discussed the outstanding Office Action telephonically with Examiner Rita Desai. Applicants' representatives agreed to amend the claims as presented in the amended presented herewith to conform to the PTO's restriction requirement and to overcome the outstanding rejection of claim 44 under 35 U.S.C. § 112, first paragraph.

Applicants kindly thank the PTO for the courtesy extended during the interview conducted by Examiner Desai.

II. The Amendments to the Claims

In the present amendment, claims 1, 10, 12-16, 20, and 44 are amended, claims 3-9, 11, 17-19, and 45-47 are cancelled without prejudice, and new claims 64 and 65 are presented for consideration. The amendments to claims 1, 10, 12-16, 20, and 44 and new claims 64 and 65 are fully supported by the application as filed. Accordingly, the amendments to the claims and the new claims do not present new matter.

In particular, support for the amendment to claim 1 may be found, for example, in claim 1 as originally filed, and in Figures 1, 2 and 3. Applicants further note that claim 1 has been amended to conform its subject matter to the restriction group of the PTO. Support for the amendment to claim 10 may be found, for example, in the specification at original paragraphs 67 and 83. Support for the amendments to claims 12-16 may be found, for example, in claims 12-16 as filed, respectively, in the specification in original paragraph 77,

and in Figures 1, 2 and 3. Support for the amendment to claim 20 may be found, for example, in the specification at original paragraphs 77 and 80. Support for the amendment to claim 44 may be found, for example, in claim 44 as filed and in the specification at original paragraphs 145 and 146.

Support for new claim 64 may be found, for example, in claims 1 and 22 as filed. Support for new claim 65 may be found, for example, in claim 22 as filed.

Applicants respectfully submit that since the specification and claims as originally filed fully support the amendments to the claims and the new claims, the amendments present no new matter. Further, Applicants respectfully submit that the amendments place the claims in condition for allowance, or at the very least, narrow the number of issues remaining for appeal. Further, Applicants note that the number of claims that would be pending following entry of the instant Amendment is fewer than the number of claims presently pending. Accordingly, entry of the instant amendment under 37 C.F.R. § 1.116 is respectfully requested. *See, e.g.*, 37 C.F.R. §§ 1.116(b)(1) and 1.116(b)(2).

III. The Amendment to the Specification

The present paper presents an amendment to the specification to clarify that which Applicants have always regarded as their invention. In particular, the amendment to the specification clarifies suitable substituents for aryl and heteroaryl moieties of the compounds of the invention. The amendment to the specification is fully supported by the application as filed. In particular, the amendment to the specification is supported in the specification, for example, in original paragraphs 76, 77, 81, 82, 83, and 86, and in claims 20 and 22 as filed. These paragraphs and claims make clear that acceptable substituents to representative aryl moieties, *e.g.*, benzene, and heteroaryl moieties, *e.g.*, carbazolyl, include each of the substituents found throughout the specification and claims as originally filed. Accordingly, the amendment to the specification presents no new matter. Entry thereof is therefore respectfully requested.

IV. Restriction and Rejoinder

The PTO has restricted the claims of the present application into seven restriction groups. Each of Groups I, II, and III relate to compounds that fall within the genus defined by formula I; group IV relates to compounds of formulae III, VI, IX, and XII; and groups V, VI, and VII relate to methods of using and/or identifying a compound of the invention.

In Applicants' last paper, Applicants provisionally elected Group II and sought to have the subject matter of Groups I and II examined together, but the PTO has maintained restriction between the two groups. Accordingly, Applicants have the cancelled subject matter of Group I to expedite prosecution of the claims. Nonetheless, Applicants respectfully submit that certain subject matter assigned to Group I by the PTO should properly be assigned to Group II. In particular, Applicants believe that the following claims belong with the other claims of Group II:

claim 10, drawn to a compound of claim 1 wherein A is benzene and B is 3-carbazoyl;

claim 12, drawn to compounds of Formula IV;

claim 13, drawn to compounds of Formula IV wherein X or Y is $-(C_1-C_2)\text{alkylene}-$, wherein C_1 or C_2 is substituted with $-\text{OH}$;

claim 14, drawn to compounds of Formula IV wherein Y is $-C_1\text{ alkylene}-$ substituted with $-\text{OH}$;

claim 15, drawn to compounds of Formula IV wherein X is $-(C_1-C_2)\text{alkylene}-$, wherein C_1 or C_2 is substituted with $-\text{N}(\text{R}_3)\text{COR}_4$;

claim 16, drawn to compounds of Formula IV wherein X is $-(C_1-C_2)\text{alkylene}-$, wherein C_1 or C_2 is substituted with $-\text{N}(\text{R}_3)\text{COR}_4$ and Y is $-C_1\text{ alkylene}-$ substituted with $-\text{OH}$; and

claim 43, drawn to a pharmaceutical composition comprising a compound of claim 1, respectively.

Applicants believe that no search beyond that necessary to examine claim 1 would be needed to examine claims 10, 12-16, and 43. Thus, examination of such claims would not present a serious burden on the PTO. In the alternative, Applicants believe that claim 1 constitutes a linking claim generic to the subject matter of claims 10, 12-16, and 43. *See* M.P.E.P. § 809.03. In either case, Applicants respectfully request that rejoinder of claims 10, 12-16, and 43 so that such claims can be examined on the merits in the instant application.

Further, Applicants again note that the claims defining the methods of groups V, VI, and VII each ultimately depend from claim 1. The PTO's attention is again respectfully invited to M.P.E.P. § 821.04, which indicates that withdrawn process claims that depend from or otherwise include all limitations of an allowable product claim will be rejoined. *See*

M.P.E.P. § 821.04. As such, upon allowance of claim 1, Applicants are entitled as of right to rejoinder of the claims of groups V, VI, and VII and allowance of such claims assuming they satisfy all other requirements of patentability. Therefore, Applicants earnestly request that the claims of groups V, VI, and VII be rejoined to the claims of group II upon allowance of such claims.

V. The Indefiniteness Rejection Should Be Withdrawn

Claim 26 stands rejected as allegedly indefinite under 35 U.S.C. § 112, second paragraph. In particular, the PTO contends that it is unclear how the R₁ and R₂ moieties recited by Formula II would form a compound where R₁ or R₂ is OH in order to yield certain of the compounds recited by claim 26.

In response, Applicants respectfully submit that the compounds of claim 26 that comprise a hydroxyl moiety in a position corresponding to R₁ or R₂ (for example, compound 3, 9, or 11) can be formed from the compounds of Formula I. In particular, such compounds can be formed by selecting X and/or Y as recited by Formula I to be C₁-C₂ alkylene substituted with OR₃, wherein R₃ is H. For example, Compound 3 can be formed when X is unsubstituted C₂ alkylene and Y is C₁ alkylene substituted with OR³, wherein R³ is hydrogen. Thus, Applicants respectfully submit that Formula I provides antecedent basis for claim 26, and that the skilled artisan can appreciate the metes and bounds of both claim 1 and claim 26.

In view of the foregoing, Applicants respectfully submit that the rejection of claim 26 as indefinite is erroneous. Therefore, Applicants respectfully request that the rejection of claim 26 as indefinite under 35 U.S.C. § 112, second paragraph, be withdrawn.

VI. The Enablement Rejection Should Be Withdrawn

Claim 44 stands rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly does not enable treatment of metabolic disorders as recited by the claim. Without acquiescing to the propriety of the rejection, and solely to expedite prosecution of the claims, claim 44 has been amended to recite a group of disorders associated with obesity. Therefore, Applicants respectfully submit that the rejection of claim 44 as not enabled by the application as filed is moot and earnestly request its withdrawal.

A. The Legal Standard

To satisfy 35 U.S.C. § 112, first paragraph, a specification must, *inter alia*, describe a claimed invention sufficiently to enable one of ordinary skill in the art to practice the

invention without undue experimentation. *See In re Wands*, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). The multi-factor test summarized by the Federal Circuit in *Wands* forms the basis for an inquiry into whether an amount of experimentation is undue.

The *Wands* factors include (1) the quantity of experimentation necessary, (2) the amount of guidance provided, (3) the presence or absence of working examples, (4) the nature of the invention, (5), the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *See id.* The test for determining whether experimentation is undue is "not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine or the specification provides a reasonable amount of guidance with respect to ... the experimentation." *See Ex parte Jackson*, 217 U.S.P.Q. 804, 807 (1982).

Finally, the PTO must establish a *prima facie* case of non-enablement in order to properly reject a claim on that basis. "When rejecting a claim under the enablement requirement of § 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention in the specification of the application..." *In re Wright*, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993). The PTO's *prima facie* case should address each of the *Wands* factors since "[i]t is improper to conclude that a disclosure is not enabling based on an analysis of only one of the [*Wands*] factors while ignoring one or more of the others." *See* MPEP § 2164.01(a), citing *Wands* at 1407. Where the PTO does not provide evidence regarding one or more *Wands* factors, Applicants presume that such factors support the conclusion that the claims at issue are fully enabled.

B. Claim 44 is Enabled by the Specification

As shown below, one skilled in the art would expect that the claimed compounds would be effective to treat the list of disorders presently recited by claim 44. The PTO's attention is respectfully invited to Exhibit A, a review article by Formiguera and Cantón. (Formiguera and Cantón, 2004, *Best Practice & Research Clinical Gastroenterology* 18(6):1125-1146; hereinafter "Formiguera")

Formiguera reviews the medical literature and identifies many specific disorders associated with obesity. For example, Formiguera teaches that type II diabetes (pp. 1130-1132), hypertension (pp.1134-1135), stroke (p. 1136), dyslipidemia (pp. 1132-1134), hyperuricemia (p. 1134), coronary artery disease (pp. 1135-1136), hypercholesterolemia (pp. 1135-1136), and atherosclerosis (pp. 1135-1136) are all significantly associated with obesity.

Thus, claim 44 recites a number of disorders that are significantly associated with obesity. Further, one skilled in the art would reasonably believe that a compound effective to treat obesity could also treat these conditions associated with obesity, in view of the significant associations among the conditions.

In view of the foregoing, Applicants respectfully submit that the rejection of claim 44 as amended for lack of enablement would be erroneous. Therefore, Applicants respectfully request withdrawal of the rejection of claim 44 as not enabled under 35 U.S.C. § 112, first paragraph.

CONCLUSION

In light of the above amendments and remarks, Applicants respectfully request that the PTO reinstate withdrawn claims 10, 12-16, and 43 and reconsider this application with a view towards allowance. The PTO is invited to call the undersigned attorney at (650) 739-3983 if a telephone call could help resolve any remaining items.

Respectfully submitted,

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